

### **REMARKS**

Claims 1 – 4, 7 – 17 and 20 were pending in the application. Claims 1, 14 and 15 have been amended herein. Claims 5, 6, 18, and 19 were previously cancelled. Support for the amendments to the claims can be found in the specification and claims as originally filed. No new matter has been added.

#### ***Rejection of Claims Under 35 USC 112, First Paragraph***

The Examiner has maintained the rejection to claims 1 – 4, 7 – 17 and 20 under 35 USC 112, first paragraph because the specification, “while being enabling for the treatment of blood clots, does not reasonably provide enablement for prevention of blood clots.” Applicants respectfully traverse this rejection.

While in no way acquiescing to the validity of the Examiner’s rejection, and solely in an effort to advance prosecution, Applicants have amended the claims to recite a method for the treatment of an extravascular hematoma or blood clot in a subject. Accordingly, the claims are enabled as written.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the foregoing rejection.

#### ***Rejection of Claims Under 35 USC 112, Second Paragraph***

The Examiner has rejected claims 14 and 15 under 35 USC 112, second paragraph as being indefinite.

Applicants have amended claims 14 and 15 so as to clarify the meets and bounds of the claims.

Accordingly, applicants respectfully request reconsideration and withdrawal of the rejections under 35 USC 112, second paragraph.

#### ***Rejection of Claims Under 35 USC 102(a)***

The Examiner has rejected claims 1-4 and 6-10 as being anticipated by Naff et al.

Enclosed herewith is a Declaration of Neal Naff and Daniel Hanley, which indicates why the authorship in the cited reference is different than the inventorship of the present application.

This Declaration establishes that the additional persons listed as an authors on the cited publication are not co-inventors of the presently claimed invention. Accordingly, it is believed that the rejection is obviated. See, *In re Katz*, 215 USPQ 14 (CCPA 1982).

***Rejection of Claims Under 35 USC 102(b)***

The Examiner has rejected claims 1 – 4, 7 – 10, 12 – 15 and 20 under 35 USC 102(b) as being anticipated by Mayfrank et al. (*Acta Neurochir (Wein)* 1993). Applicants respectfully traverse the rejection.

To anticipate a claim, each and every element of the claim must be found in a single reference. This is discussed in the Manual of Patent Examining Procedure § 2131:

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). “The identical invention must be shown in as complete detail as is contained in the . . . claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

The Mayfrank reference does not teach or suggest a method for the treatment of an **extravascular hematoma** or blood clot in a subject, comprising administering to the subject a therapeutically effective amount of a thrombolytic agent, wherein the thrombolytic agent is tissue plasminogen activator (t-PA) or recombinant tissue plasminogen activator (rt-PA), thereby preventing or treating the extravascular hematoma or blood clot.

The Mayfrank reference teaches treatment of intraventricular hemorrhage with rtPA. The Mayfrank reference shows that injection of rtPA via a ventricular catheter is used to dissolve intraventricular blood clots. (see p.37) Nowhere does the Mayfrank reference teach

Accordingly, Mayfrank et al. does not anticipate the claimed invention. teach or suggest a method for the treatment of an **extravascular hematoma** or blood clot in a subject.

Applicants respectfully request reconsideration and withdrawal of the foregoing rejection.

***Rejection of Claims Under 35 USC 103(a)***

The Examiner has rejected claims 1 – 4, 7 – 17 and 20 as being unpatentable over Naff et al. in view of Wright et al.

As discussed above, Naff et al. is not a prior art against the instant invention as it is published by the Inventors not more than 1 year prior to the priority date of the instant application.

Accordingly, the foregoing rejection is obviated by the removal of the Naff et al. reference as art against the instant application. Wright et al. alone does not render the pending claims unpatentable.

Applicants respectfully request reconsideration and withdrawal of the foregoing rejection.

The Examiner has rejected claims 11, 16 and 17 as being unpatentable over Mayfrank et al. as applied to claims 1 – 4, 7 – 10, 12 – 15 and 20 above.

The Examiner argues that the Mayfrank reference “differs from the instant claims 11, 16 and 17 insofar as it does not teach a 4-hour interval, or stopping treatment when the blood clot is 80% of its original size, or when the blood clot is 80% of its original size about 3 days after the first administration of the thrombolytic agent.” (Office Action, p.5). The Examiner argues that “(i)t would have been obvious to a person having ordinary skill in the art to administer the rtPA of Mayfrank et al. at about 4 hours, since the term “about” is inclusive of higher or lower values.” (Office Action, p.5).

Claims 11, 16, and 17 depend from claim 1.

As pointed out above, the Mayfrank reference does not teach the invention as claimed. In particular, Mayfrank does not teach or suggest a method for the treatment of an **extravascular hematoma** or blood clot in a subject.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the foregoing rejection.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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